The history of c/c valve litigation demonstrates that preemption is repeatedly raised and litigated, with inconsistent results. For example, while the Third Circuit in *Michael* held that a claim alleging breach of express warranty was not preempted, the court in *Kemp v. Pfizer, Inc.*, 851 F. Supp. 269, 273-74 (E.D. Mich. 1994)—which involved the same express warranty as *Michael*[5]—held just the opposite, ruling that this claim was preempted by § 360k(a). Contrary to the Third Circuit, which found this Court's decision on express warranty in *Cipollone* applicable to MDA preemption of that claim, the *Kemp* court reasoned that "given the differences in the [MDA and Smoking Act] statutes, the analysis undertaken in *Cipollone* is distinguishable." 851 F. Supp. at 273 n.1.

Similarly, in *Burnett v. Pfizer, Inc.*, 864 F. Supp. 25, 26 (E.D. Ky. 1994), the court held—also contrary to the Third Circuit's decision in *Michael*—that a fraud claim regarding Shiley's conduct in connection with the c/c valve was preempted by the MDA. *Contra Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426 (C.D. Cal. 1994) (holding that express warranty and fraud claims regarding the c/c valve were not preempted).

In sum, there is ample basis for a grant of certiorari to avoid repeated litigation and appeals of the preemption issue in the lower courts.

Shiley's request to withdraw the FDA's pre-market approval ("PMA") for the c/c valve, after Shiley ceased marketing the valve, does not undercut this case's applicability to the gen-

---

fear of future fracture of a working c/c valve. As to "fracture" (malfunction) and "reoperation" (replacement) claims, *Bowling* merely requires a formula-based automatic settlement offer, which the claimant is free to reject. Many claimants do reject these offers, including, for example, the plaintiff in *Saitta, supra*, who is represented by the same law firm that is co-counsel to respondent Michael in this case.

[5] As in *Michael*, the express warranty at issue in *Kemp* was a "warranty of reasonable care in the manufacture of the artificial heart valve at issue." 851 F. Supp. at 273.

eral run of medical device product liability litigations. (*See* Opp. Br. at 20-21). Every medical device is eventually withdrawn from the market and replaced by new models, particularly so in the rapidly developing field of replacements of human organs or parts thereof. The fact that the c/c valve is no longer being implanted is neither relevant, nor unusual.

Withdrawal of the PMA is equally irrelevant. The court below, in holding that most of respondent's claims were preempted, necessarily concluded that withdrawal of the PMA did not affect preemption; and respondent has filed no cross-petition seeking review on that issue.[6] Moreover, the court below was plainly correct in rejecting this argument. "If the preemption protection afforded by the MDA were removed once a faulty device was pulled from the market, then the fear and hesitancy in developing original and ground-breaking medical devices that Congress meant to alleviate would always remain as a bar to the development of needed devices that are potentially dangerous". *Kemp*, 835 F. Supp. at 1023.[7] If an implied exception were created to the express preemption doctrine for medical devices that are no longer sold or have a current PMA, that exception would swallow the rule. Artificial replacements for human organs or vital organ parts are continually being withdrawn from use and replaced by improved devices. Holding that the benefits of federal preemption are retroactively lost where a PMA has been voluntarily withdrawn, or terminated for any reason, would mean that virtually every federally-regulated medical device ultimately would be subject to retroactive state requirements—squarely contrary to Congress' express intent in enacting § 360k.

---

[6] The district court, in its decision, explicitly held that withdrawal of the PMA makes no difference. App. at 50a-51a n.11.

[7] *Accord Hamilton v. Surgidev Corp.*, 1993 WL 533994 (E.D. La. Dec. 10, 1993) (preemption despite withdrawal of intraocular lens and its IDE exemption); *Cameron v. Howmedica*, 820 F. Supp. 317 (E.D. Mich. 1993) (claim based on artificial hip which had 25% failure rate and had been removed from the market after two years held to be preempted).

The various other facts that respondent discusses in her opposition brief, principally at pp. 3-8, also have nothing to do with the legal issues raised by the Petition. They are simply respondent's alleged facts in support of her fraud and breach of warranty claims, all of which would be controverted and/or placed in proper context at trial if the claims are not held preempted.[8]

---

[8] The Third Circuit did not find any of these alleged facts, but merely assumed them to be true for purposes of ruling on the grant of summary judgment (App. at 7a). Moreover, of the two documents on which respondent principally relies, one is a report prepared in 1990 by the majority staff of a Congressional subcommittee—it is not a "Report of the Subcommittee" or a "House Report" as respondent disingenuously cites it (Opp. Br. at 4 n.2). The other document is a memorandum by three FDA employees that was never adopted by the agency. These documents are inadmissible. *See, e.g., Baker v. Firestone Tire & Rubber Co.*, 793 F.2d 1196, 1199 (11th Cir. 1986) (subcommittee report "consisted of the rather heated conclusions of a politically motivated hearing"). *Accord Pearce v. E.F. Hutton Group, Inc.*, 653 F. Supp. 810, 816 (D.D.C. 1987); *Knight Pub. Co. v. U.S. Dept. of Justice*, 631 F. Supp. 1175, 1178 (W.D.N.C. 1986). *Toole v. McClintock*, 999 F.2d 1430, 1433-34 (11th Cir. 1993) ("The tentative and second-hand nature of the findings in the FDA report should have kept it out of evidence"; reversing judgment for plaintiff). Further, while petitioners in 1994 settled claims under the False Claims Act, there was no "fine" and no finding or admission of liability. (Opp. Br. at 8-9 n.7).

CONCLUSION

For the reasons stated above, and all the reasons set forth in the Petition, Certiorari should be granted.

Dated: August 30, 1995

Respectfully submitted,

DAVID KLINGSBERG
KAYE, SCHOLER, FIERMAN,
HAYS & HANDLER
425 Park Avenue
New York, New York 10022
(212) 836-8000

Counsel of Record for Petitioners